

Amendments to the Specification:

At page 2 of the Specification:

Ko et al., “Emulsion formulations of testosterone for nasal administration”, J. Microencaps, 15(2): 197-205 (1998), proposed the used of charged testosterone submicron O/W emulsion formulations (water/TWEEN80), soybean oil/SPAN80) based on the hypothesis that increased absorption is possible upon solubilisation of the drug and/or prolongation of the formulation residence time in the nose. He found a higher relative bioavailability of the positively (55%) and negatively (51%) charged emulsion compared to the neutral one (37%). Tmax was observed in every case at about 20 min after administration. It is difficult to discuss these results because Ko did not take blood samples before application and thus it is not possible to evaluate the differences in the decrease of serum levels, although from a graph it seems that after intravenous application (hydroalcoholic solution) the level shows the longest elimination half time. In practice, however, such an emulsion is not suitable because the droplet size (430 nm) is not acceptable for nasal application.

At page 8 of the Specification:

Component (C) shall comprise at least a surfactant such as, but not limited to, lecithin, fatty acid ester of polyvalent alcohols, of sorbitanes, of polyoxyethylensorbitans, of polyoxyethylene, of sucrose, of polyglycerol and/or at least one humectant such as sorbitol, glycerine, polyethylene glycol, or macrogol glycerol fatty acid ester. Particularly useful, however, are oleoyl macrogolglycerides (such as LABRAFIL M 1944 CS, as available from Gattefossé (Franco)).

The term “viscosity regulating agent” shall mean a thickener or gelling agent. Examples are, but not limited to, cellulose and derivatives thereof, polysaccharides, carbomers, polyvinyl alcohol, povidone, colloidal silicon dioxide, cetyl alcohols, stearic acid, beeswax, petrolatum, triglycerides or lanolin. Particularly useful, however, is colloidal silicon dioxide (such as Aerosil 200, as available from Degussa).